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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,276	04/15/2000	GLENN F. SPAULDING	010-US-002	9303

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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/06/2003

Handwritten signature

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,276

Applicant(s)

SPAULDING, GLENN F.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10, 11, 13-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 11, 13-31, and 33-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 6/24/03 in Paper No. 20, is acknowledged and has been entered. Claims 13 and 25 have been amended. Claim 12 has been cancelled. Accordingly, claims 1-4, 10, 11, 13-31, and 33-34 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. The rejection of claim 12 is now moot in light of Applicant's cancellation of the claim.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 10, 11, 13-31, and 33-34 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-4, 10, 11, 13-18, 22, 24-31, and 33-34 stand rejected under 35

U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) in view of Walters (US 6,135,940) for reasons of record.

5. Claims 1, 4, 10, 13-18, 22, 26-29, 31, and 33-34 stand rejected under 35 U.S.C.

103(a) as being unpatentable over Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940) for reasons of record.

6. Claims 19-20 and 23 stand rejected under 35 U.S.C. 103(a) as being

unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Surmodics, Inc. for reasons of record.

7. Claims 2 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable

over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Saralegui et al. (US 5,439,645) for reasons of record.

Response to Arguments

8. Applicant's arguments filed 6/24/03 have been fully considered but they are not persuasive.

A) Applicant argues that the term “adapted to” should be acceptable in light of the specification; thus, it is clear what is intended by the term “adapted to” if read in light of the specification.

In response, there appears to be no specific or figurative “modification” or “adaptation” described in the specification to encompass or delimit the structures, i.e. light source or detector, that are recited as being adapted to illuminate or detect differentially. Accordingly, this rejection has been maintained.

B) Applicant argues that Cottingham does not describe or fairly suggest the rotation of a sample along its longitudinal axis or the simultaneous rotation and interrogation of a sample via a light source. Applicant further contends that Walters which is cited in combination with Cottingham teaches incremental (discrete) rotation of a sample vial which is held stationary with respect to the detector during interrogation.

Contrary to Applicant argument that Walters takes measurement readings only at increments when the sample vial is held stationary, Walters, indeed, discloses that light source illuminates the transparent cylindrical tube and the detector means detects and obtains optical readings from a light reflected from the cylindrical tube, while the cylindrical tube is being rotated by the rotating means at lowered speeds of 1,000 to 2500 rpm at page 11, lines 3-13, just as recited in the claimed invention. In response to applicant's argument that the mere fact that references can be combined or modified does not render the resultant combination obvious, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the

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structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

C) Applicant argues that Anderson is directed to “a method for separating microorganisms ... from a mixture by two dimensional centrifugation.

In response, the claims do not appear to exclude that claimed apparatus is used for a method of separating microorganisms ... from a mixture. Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

D) Applicant argues that the tubes and apparatus as taught by Anderson et al. do not spin about their longitudinal axis and neither Anderson or Walters teach, describe, or fairly suggest that discrete rotation and fixed interrogation scheme of Walters can be combined with the centrifuging motion and fixed position interrogation of

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Anderson. Applicant contends that Examiner relies on hindsight reconstruction for the motivation to combine the references.

Contrary to Applicant argument that Walters takes measurement readings only at increments when the sample vial is held stationary, Walters, indeed, discloses that light source illuminates the transparent cylindrical tube and the detector means detects and obtains optical readings from a light reflected from the cylindrical tube, while the cylindrical tube is being rotated by the rotating means at lowered speeds of 1,000 to 2500 rpm at page 11, lines 3-13, just as recited in the claimed invention.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms, i.e. cells, in a sample. The apparatus is

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specifically used for measuring fluorescence from the cellular sample contained in a transparent cylinder. The apparatus comprises a rotating means for rotating the transparent cylinder, a light source such as laser, detector and optical filters for detecting light passing through or emitted from the sample. Walters is combined with Anderson only for the disclosure of rotation of the transparent cylinder along a longitudinal axis of the transparent cylinder. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the teaching of Walters into the apparatus of Anderson et al. because Walters specifically taught such embodiment of an apparatus that allows a cylindrical fluid tube to rotate along its longitudinal axis while rotating the cylindrical tube in a traverse direction provides capability to obtain optical readings of the centrifuged sample from different locations about the circumference of the cylindrical tube.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 2, 2003

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GROUP 1800-691